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BELOW-KNEE PROSTHESIS DESIGN CONSIDERATIONS

FRANK KING ELLIS

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BELOW-KNEE PROSTHESIS DESIGN CONSIDERATIONS

by

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Lieutenant Commander, United States Navy
B. S., University of Colorado, 1956

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ABSTRACT

A brief summary of the historical development of artificial limbs is followed by a detailed history of the below-knee prostheses worn by the author. Next, the development of a method of obtaining a precision, weight bearing impression of an amputation stump using a low exotherm, two-component froth foam, with a method of evaluating a prosthesis socket made from said impression, is given. Finally, some experimental research into the design of an inexpensive, miniature transducer for measuring localized pressure between the amputation stump and the prosthesis socket is discussed.

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LIST OF DEFINITIONS

Term	Definition
articulated	Jointed.
atrophy	A wasting away of the body.
biomechanics	Mechanics of the body.
condyle	A rounded protuberance on a bone, serving to form an articualtion with another bone.
distal	Situated away from the point of origin or attachment, terminal.
dorsal	Pertaining to the back (top of the foot).
fibula	The outer and thinner of the two bones of the lower leg.
Muley prosthesis	As used in this thesis, a below knee artificial leg carved from wood to fit the stump, having an open ended socket (hollow wooden cylinder), suspended by a suprapatella cuff.
orthopedics or orthopaedics	The correction or cure of deformities and diseases of the skeletal system (bones, joints, muscles).
patella	The kneecap.

Term	Definition
plantar	Pertaining to the sole of the foot.
popliteal	Pertaining to the part of the leg posterior to the knee.
posterior	Of or pertaining to the dorsal side of man.
prosthesis	An artificial part to supply a defect of the body.
prosthetist	One who builds prostheses.
proximal	Situated toward the point of origin or attachment.
Patellar Tendon Bearing (PTB) prosthesis	A below-knee artificial leg made from laminated plastic, having a closed ended socket, designed to load the patellar tendon, suspended by a suprapatella cuff.
sphygmomanometer	An instrument for measuring the pressure of the blood in an artery.
tibia	The shinbone, the inner and larger of the two bones of the lower leg.

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SECTION 1

HISTORICAL DEVELOPMENT OF ARTIFICIAL LIMBS

1.1 Ancient Times

Man has been endowed by his Creator with upper extremities for manipulating objects, lower extremities for ambulating and most important, a creative mind for devising artifical replacements (prostheses) for these extremities or portions thereof should they be amputated due to disease, deformity, accident or battle. McDaniel[1] mentions that one of the first records of this creative genius was found in a 2830 B.C. carving on the portal of Hirkouf's tomb where a crutch was shown replacing an amputated leg.

Major[2] states that the oldest book of the Veda period of India (about 1500-800 B.C.) makes mention of the use of artificial legs, teeth and eyes. It is assumed by Fleigel[3] that endemic diseases, cruel civil punishments, war injuries, and inhuman maiming of war prisoners during this period provided the motivation for the production of these prosthetic devices even though no historical records were found to corroborate this assumption.

One of the most well-known stories of early prostheses was related by Herodotus[4]. He tells of Seer Hegesistratos of Elis who, with one foot held in the stocks, was imprisoned by the Spartans and condemned to death in 484 B.C. Hegesistratos obtained a knife, amputated his foot, escaped and built a wooden foot for himself after the wound healed. According to the Orthopaedic Appliances Atlas[5], "...... he stumped about as sooth-sayer to the Persian Army until he was recaptured and put to death by the Spartans."

A vase found in southern Italy and reportedly dating back to the fourth century B.C. shows the figure of a man supported by a knee-length peg leg on one lower extremity and a wooden capsule replacing the foot of the other lower limb[3].

The oldest known artificial leg ever on display was built during the Samnite Wars (300 B.C.). A description of this prosthesis according to Shufeldt[6] states, "Roman artificial leg; the artificial limb accurately represents the form of the leg; it is made with pieces of thin bronze, fastened by bronze nails to a wooden core. Two iron bars, having holes at their free ends, are attached to the upper extremity of the bronze; a quadrilateral piece of iron, found near the position of the foot, is thought to have given strength to it. There is no trace of the foot and the wooden core has been entirely crushed away. The skeleton has its waist surrounded by a belt of sheet bronze edged with small rivets, probably used to fasten a leather lining."

The first known artificial hand was made of iron for Marcus Sergius, a Roman general, who lost his right hand during the second Punic War (218-201 B.C.). This hand was reportedly used in battle with dexterity by Sergius[5].

Epstein[7] in his translation of the Talmud reveals the concern of Rabbi Meir and Rabbi Jose over whether or not a man wearing a wooden leg violates the Sabbath law forbidding the carrying of objects. This protion of the Talmud was completed in the second century A.D. The prosthesis involved was described as a hollowed, wooden log containing pads upon which to place the stump.

1.2 Middle Ages

Records of artificial limbs used during the Middle Ages are noticeably lacking. A medical and surgical regression during this period of recorded history might explain part of the reason for this situation. There is no indication of any advance in the design of prosthetic devices. To the contrary, there is evidence of amputees having their stumps bound in wooden splints, and lower extremity amputees propelling themselves on moveable benches[5].

1.3 Fifteenth Century to the Civil War

Chronologically the next recorded advance in prosthetic devices was the Alt-Ruppin hand found along the banks of the Rhine with pieces of armor which enabled dating the limb at about 1400. The device was made of iron with the hand jointed at the wrist to a perforated iron sleeve into which the stump fit. The thumb was rigid while the fingers moved in pairs and were controlled by bottons at the base of the palm. Some of the hands of this period incorporated jointed fingers with variable flexion operated by the normal hand controlling a ratchet device[8].

A sixteenth century lower limb from Putti[9] shows an iron prosthesis with construction similar to that of the hand just described except that all joints were rigid. Wilson[10] indicates that this limb was typical of lower extremity prostheses for the upper class of the day. It was made of iron (probably by an Armorer) and was designed for the aesthetic purpose of hiding the missing limb of a mounted knight rather than for the functional purpose of supporting the amputee's weight. The artificial hands of that era incorporated both design principles (aesthetically appealing and functionally sound) since they were used to grasp a battle weapon.

Conditions for the amputee in lower classes were just reversed. For them the need for upper extremity prostheses was far outweighed by the greater need for improved locomotion provided by functional, weight bearing lower extremity artificial limbs. These limbs likely were the wooden peg leg type made by a carpenter or the individual amputee himself.

Probably the single greatest contribution to surgical techniques and prosthetic appliance design can be attributed to the French surgeon, Ambroise Paré (1510-1590). Until his time, amputation stumps were generally crushed or covered with boiling oil to control hemorrhage after surgery (practiced by some as late as the mid-18th century). Such treatment left very few stumps suitable for operating a functional prosthesis. Not only did Paré use ligatures to control bleeding during surgery and choose a site of election for amputation, but he also designed prostheses for his patients.

The artificial limbs designed by Paré were built by a skilled locksmith, "le petite Lorrain". One such limb was built for an above-knee (AK) amputee. It consisted of a socket for the stump mounted on a pylon with a foot attached to it. The entire metal device was covered with sheet metal plates resembling armor. Unique features included a foot hinged at the tarsal section and spring loaded to the unflexed position plus a locking knee joint permitting a stiff knee for walking or a flexed knee for horseback riding[5,3].

Wilson[10] states that the first known below-knee (BK) prosthesis incorporating a knee joint was built in 1696 by Verduin, a Dutch surgeon. Verduin's prosthesis consisted of a wooden foot joined to a leather lined copper socket. Two lateral steel bars, hinged at the knee, extended vertically from the socket up to a leather thigh cuff designed to carry a portion of the total body weight. This concept existed for several decades before it was accepted, but it then became the forerunner of the conventional BK prosthesis of today.

In 1812 the centuries old challenge to construct an artificial hand with good functional properties plus pleasing cosmetic characteristics came closer to a solution through the efforts of a Berlin dentist, Peter Ballif. Ballif's hand incorporated articulated finger joints controlled automatically by remaining body muscles. Synchronous finger movement was controlled by elbow motion. One disadvantage of this prosthesis was the numerous straps required for its operation[5].

Lighter weight lower extremity prostheses were introduced when James Potts of London patented his design. The leg consisted of a wooden socket, shin, ankle joint and foot, steel knee joints and artificial tendons to facilitate push off during walking. Since such a limb was built in 1816 for the Marquis of Anglesea who lost a leg in the Battle of Waterloo, it acquired the name Anglesea leg. Potts used a similar design incorporating a wooden thigh socket for AK amputees[3,5].

The Anglesea leg came to the United States in 1839 via a Potts workman, William Selpho of New York, who altered the prosthesis slightly by inserting a rubber plate in the ankle joint to reduce jarring and adding a rubber sole to the foot for greater elasticity and friction[5].

In 1846 an amputee, Dr. Benjamin F. Palmer of Philadelphia, improved and patented the Selpho prosthesis. The Palmer AK leg consisted of hollow wooden thigh and lower leg pieces, metal knee and ankle joints (bolts through fixed metal plates in upper foot and lower thigh pieces) with friction bearings, spring action toe joint and catgut "tendons" for coordinated knee and ankle motion. The Palmer leg improved by various limb makers (prosthetists) became known as the American leg and was used widely in America, England, and France up until World War I[3,5].

A ball-and-socket ankle joint incorporating an ivory ball and a vulcanized rubber socket was introduced by Dr. Bly in 1858[5].

Marks, in 1860, replaced wooden feet with feet made of vulcanized rubber newly developed at that time by Goodyear Rubber Company. Such feet eliminated the need for an ankle joint[5].

1.4 Civil War to the Present

J. E. Hanger was one of the first Southerners to lose a leg in the Civil War. In 1861 he used adjustable rubber bumpers at the ankle joint to control plantar and dorsal flexion of the artificial foot. Until recently, this design was used almost universally[5,10].

The idea of holding a prosthesis on the stump with air pressure alone and dispensing with conventional straps and/or belts was patented by Dubois D. Parmelee of New York in 1863. His suction socket concept, as it is known and widely used today, failed to be accepted for almost ninety years[5].

The Civil War (1861-1865) created the need for Union Army surgeons alone to perform nearly 30,000 amputations. With such impetus to spur further developments in artificial limb design, it is somewhat surprising that greater improvements were not realized in designing limbs. Frequently the achievements attained were the results of amputees designing their own prostheses.

In 1865 Herrmann of Prague introduced aluminum to replace steel components in artificial limbs.

World War I caused 4,403 major amputations in American troops; 42,000 in British forces and approximately 300,000 in all the armies of Europe. Wilson[10] mentions that due to America's relatively small number of war amputees combined with the economic depression of the Thirties, interest in the advancement of artificial limbs soon waned and little progress in the field of limb prosthetics was made between the two World Wars[5].

This situation was not as prevalent in England where Marcel Desoutter introduced pelvic suspension for securing an AK prosthesis to the amputee. This reduced the discomfort and eliminated the shoulder shrugging existing with the original shoulder suspension. Desoutter also developed the first all aluminum light weight prosthesis in 1912[3].

Some of the more significant advances for the prosthetic industry during this period came in the form of better understanding and improved methods of approaching the overall problem. At Roehampton, England in 1915, an amputee center was established where a marriage of the ideas of the surgeon with those of the prosthetist could be achieved. Later the Ministry of Pensions provided for prosthesis (and a spare) procurement, repair, and replacement for an amputee for the remainder of his life[5].

In the United States, the Association of Limb Manufacturers of America was founded in 1917 to insure ethical practice within the industry. In addition, amputee veterans were grouped in specific hospitals where specialized surgical and prosthetic care and training could be administered. Now the surgeon began to be concerned about the amputee's total rehabilitation after surgery and the prosthetist began to assume the professional dignity commensurate with his responsibilities. Hadden, a prosthetist, and Thomas, a surgeon, both from Denver, emphasized that best end-results could be achieved if prosthetist and surgeon worked together for the most critical parameters in prosthesis design — fit and alignment[5,10].

During World War II some 17,130 American troops became amputees requiring prosthetic appliances. Once again the greater developments were in the areas of education, research, legislation, etc. rather than actual prosthetic hardware. In 1943 ten amputation centers were established in the United States to provide surgery, prosthesis fitting, training of amputees and training of prosthetists. In the same year a limb of standard design was planned for rapid procurement, easy fitting, and easy modifying to accommodate a changing stump[5].

The Artificial Limb Program was launched in 1945 by the Surgeon General of the Army. The program involved contracting with universities and industries in an attempt to solve various aspects of the overall problem. In 1948 Congress passed Public Law 729, allowing itself to annually appropriate $1,000,000 to the Veterans Administration for research in prostheses, orthopaedic appliances, and sensory aids. Responsibility for fundamental research in the biomechanics of upper extremity prostheses was given to the University of California at

Los Angeles (UCLA), and that for lower extremity prostheses to the University of California at Berkeley (UCB)[5].

Northrop Aircraft, Inc. developed an elbow unit capable of being locked or unlocked merely by utilizing the energy from the body harness. This advancement left the other arm free and, further, made it possible for an amputee with an upper extremity amputated at any level to have a functional prosthesis[5].

Probably the single greatest advancement in materials used for constructing artificial limbs was the use of plastic laminates. These materials provided strength, light weight, rapid manufacture and a pleasing cosmetic appearance for prostheses[5].

During this post-war period the suction socket mentioned earlier came into wide use in America largely due to its high degree of refinement and wide use during World War II in Germany. This improved socket spawned an awareness of the need for further studies and improved techniques in the critical areas of fitting and alignment. The need was subsequently filled by the scientific, systematic fitting and alignment procedures developed by the University of California[3,5].

As previously mentioned, the conventional BK prosthesis consisting of a wooden socket and shin, metal side bars hinged at the knee and a leather thigh corset was a direct result of the Verduin leg of 1696. The patellar tendon bearing (PTB) prosthesis represented a significant simplification and refinement of the conventional BK limb. In the PTB prosthesis, side bars and the thigh corset are eliminated. The socket made of laminated plastic can be used as is (hard socket) or used with a rubber/leather insert (soft socket). Primary weight bearing areas of the PTB are patellar tendon, popliteal area and tibial condyles.

The prosthesis is held on the stump by a cuff or strap fastened around the thigh just above the patella.

The most significant recent BK prosthesis advancement appears to be the development of the Air Cushion Socket by UCB in 1965. This socket is discussed in greater detail in Section 2.7.

SECTION 2

PROSTHETIC HISTORY OF THE PATIENT

2.1 Aircraft Accident and Hospitalization

On 11 July 1962 at NAS Point Mugu, California, the author (hereafter referred to as the patient) was involved in an aircraft accident that left him with minor lacerations and burns on his head, shoulders and arms; three fractured ribs; a fractured back; his left leg fractured in several places below the patella and his right leg traumatically amputated below the patella. The several operative attempts to save the patient's left leg proved futile, so in September it was surgically amputated some six inches distal to the patella.

Hospitalization for the patient consisted of two weeks spent in St. John's Hospital in Oxnard, California followed by fourteen weeks at the U. S. Naval Hospital in San Diego, California. Due to infection in the left leg, the patient's course steadily worsened until the amputation was performed in September. At that time his course improved rapidly.

Both the prostheses and the amputation stumps mentioned throughout the discussion that follows are those of the patient. The right stump measures 9-3/4 inches from mid-patella to distal end, contains no fibula, but does have considerable muscle tissue remaining. The left amputation stump from mid-patella to distal end is 6-1/4 inches long, contains both tibia and fibula, but has practically no muscle tissue left as a result of the severe post-accident infection. These stumps are shown in Fig. 1.

2.2 First Muley Prostheses

In September 1962 a standard wrap cast was made by a prosthetist from Physicians Orthopedic Service, San Diego, California of the patient's right stump by applying plaster impregnated gauze bandage over a damp cast sock pulled snugly over his stump and marked with an indelible pencil to indicate scar tissue, bony prominences, patella, tibial crest, etc. (Fig. 2). This cast was made in order to reproduce the surface contour of the stump and ultimately serve as a pattern for the carving of a wooden socket for the prosthesis. During the wrap process, the patient was seated in a chair with his knee flexed about 20 degrees. While the plaster hardened, essentially no external forces were applied to the wrap (unloaded stump) which is shown in Fig. 3. The entire process represented a new experience for the patient, who was impressed and curious about each step in addition to anticipating favorable results.

In November 1962 a similar procedure was followed by a different prosthetist at Physicians Orthopedic Service in order to obtain an impression of the left stump. This time the patient observed some basic differences incorporated in the method of marking the damp cast sock and in applying the plaster wrap. Though he felt he was too much of a novice in the field to comment on these differences, the patient did begin to wonder if there might not be a better way to make the impression in order to eliminate these seemingly significant differences. From the impressions so made, and after various minor socket modifications, a pair of quite functional Muley legs were hand carved from willow wood.

2.3 Second Muley Prostheses

By August 1963 the stumps had atrophied significantly, and the first set of prostheses had been modified many times. Hence, a new set of the same type of Muley legs had to be built at Physicians Orthopedic Service. Once again wrap casts as previously described were taken, and again significant differences in technique were noted. This time, however, the patient observed the entire process from impression to finished prothesis closely, asking numerous "why" questions at each stage of the construction. The resulting feeling was that with the materials and technology available to the U.S.A. in 1963, there must be a more precise way to obtain the impression and a more rapid method of constructing the socket.

2.4 First PTB Prostheses

Having performed well on the Muley limbs, and having been returned to a limited flight status in the Navy, the patient was invited to evaluate a pair of the PTB prostheses currently being made of reinforced plastic by the Navy Prosthetic Research Laboratory (NPRL), Oakland, California. In February 1964 wrap casts were made at NPRL in a similar manner as previously done, except this time a force was applied by the prosthetist's thumbs pressing on the patellar tendon just below the patella and his fingers pressing on the popliteal area posterior to the patella (Fig. 4). This created the end result of having a very pronounced convex bulge inside the patellar region of the finished socket (patellar shelf) and a lesser convex bulge inside the socket's popliteal area (popliteal bulge).

The wrap seemed to approach the "real" conditions since it was more of a form-fit and the stump was at least loaded in two areas during the process. The materials and the techniques used seemed to be more current, but the fit and the functional capabilities of the completed limbs were very poor. The patient's critique on these, his latest set of prostheses, was described tersely as "totally unsatisfactory". He did feel, however, that the potential and the materials were available to do better in the construction of BK artificial limbs.

2.5 Second PTB Prostheses

Back in San Diego the patient began questioning the prosthetists at Physicians Orthopedic Service about the latest materials and methods used in BK limb construction — wondering specifically about the use of plastics for both impression taking and socket material. He was advised that all plastics then in use exuded far too much heat (high exotherm) while hardening to be tolerated by the stump during impression taking, but that good results had been obtained in building plastic sockets for the PTB prostheses from conventional plaster casts.

As a result of these discussions plus a desire to experiment with a fabrication process that seemed to have excellent potential, a second set of reinforced plastic PTB legs was made for the patient by Physicians Orthopedic Service in March, 1964. Wrap casts were made as before for the PTB method holding similar patellar tendon and popliteal area pressures, but once again significant variations were incorporated. The finished sockets resulting from this process were quite uncomfortable, but still the patient felt the method and materials used could be developed into a better method of producing BK artificial limbs. The experiment strengthened his feelings that some sort of plastic could be used in making a more precise impression.

2.6 Third PTB Prostheses

On 17 May 1964 the patient was invited to return to NPRL for research in the design and construction of below-knee artificial limbs for a period of about three weeks. Problem areas, desirable features and general fabrication methods were discussed. It was agreed that the plastic PTB prostheses planned should include as many of the features considered desirable as possible. The prosthetist involved used extreme patience and care in all phases of construction: marking the damp cast sock; applying the plaster wrap; holding patellar tendon and popliteal pressures during cast set-up; removing and drying the wrap; building and modifying (to provide relief areas) the positive stump reproduction made from the wrap cast; building the socket; joining and aligning the socket, shin and foot; attaching the suspension straps; and finally making minor socket adjustments. The end result was an excellent pair of prostheses in both fit and performance.

During the three week period at NPRL the patient had the opportunity to question the staff about the possibility of getting an impression of the stump while it was bearing weight in some type of plastic, foam or plaster. They too advised him that all of the foams and plastics they were aware of had too high an exotherm to be tolerated by the human body, but that years earlier at NPRL quite accurate impressions had been obtained from an amputee "standing" in a container of dental stone. One such impression was made with the patient bearing near total body weight on his rather irregularly shaped left stump. Both NPRL personnel and the patient were favorably impressed with the exactness of the reproduction and with the fact that the stump had endured fairly comfortably almost full weight (loaded stump).

This experiment served to strengthen the patient's beliefs that with the proper plastic or foam not only could a precise impression of a stump in a loaded condition be easily obtained, but quite possibly this impression could be used as the socket itself - thus creating a rapid, inexpensive, uncomplicated method of building artificial limbs anywhere in the world. He felt that each square inch of the stump could carry, and should be required to carry, a portion of the total load both for overall health of the stump (massage action to stimulate circulation) and for optimum load distribution considerations (minimize high pressure areas).

2.7 First Air Cushion Socket Prostheses

During June 1965 the distal end of the patient's right stump became ulcerated on a portion of the scar tissue. This condition was accompanied by significant swelling and finally complete breakdown of the tissue circumferentially about two inches above the stump's distal end. At that same period of time the University of California's Biomechanics Laboratory in San Francisco was engaged in evaluating a new type of below-knee prosthesis socket (PTB Air Cushion Socket) which they had developed.

The new socket is quite similar to the PTB socket, but the air cushion concept incorporates air at atmospheric pressure entrapped between the socket wall and a rubber bladder built into the lower 2/3 to 3/4 of the socket. The result is a rather even distribution of pressure (slightly higher right on the distal end) over a large distal portion of the stump and stimulation of circulation through massaging action. Due to the patient's current problem plus earlier lesser complaints about his prostheses, it was decided by NPRL and the University of California prosthetist that the patient should be fitted by the University with the new type of artificial limbs.

In July 1965 the wrap casts were made similarly to earlier PTB wraps except that the prosthetist applied a firmer wrap and held more constant patellar and popliteal pressures than previously experienced. During construction and fitting of the prostheses the prosthetist's rapid detection of problem areas, positive corrective actions and overall superior understanding of the entire process was readily apparent.

The end result constituted production of the most comfortable pair of limbs worn by the patient to that date (Fig. 5). It is felt that this was due in part to the ability of the prosthetist and in part to the better design incorporated in the air cushion socket. The new prostheses were put on while the patient's right stump was badly swollen, open and draining. Within two weeks the stump had completely closed, and within two months both stumps looked healthier than they had at any time since the amputations. The air cushion socket represented a more intimate fit with greater stump surface area carrying a portion of the total load. This result served to strengthen earlier beliefs that it would be desirable to take foam impressions of a loaded stump.

2.8 Conclusions and Purpose for Continued Research

From the various sets of prostheses built and discussed in this Section, the patient felt that the single greatest obstacle to the design of a satisfactory BK artificial limb was the method of obtaining the initial negative cast of the amputation stump. It appeared that too much latitude in the final socket dimensions occurred as a result of significant variations employed in taking the wrap cast and in modifying the resulting positive cast. It was also concluded that a comfortable socket (likely the result of optimum load distribution) was the most significant design parameter involved in providing the amputee with the most functional prosthesis possible.

The purpose of the patient's continued research into this problem was to develop a method of obtaining an accurate impression of the stump in a loaded condition with soft tissues compressed. It was felt that a more optimum distribution of the stump's loading could be achieved from such an impression, thus reducing high concentrated loads, minimizing modifications during fitting and increasing the amputee's comfort and activity level. Ultimately it was hoped that the impression material could be used as the finished socket directly as discussed in Section 4.

SECTION 3

DEVELOPMENT OF PRECISION, WEIGHT BEARING AMPUTATION STUMP IMPRESSIONS

3.1 Concept and Discovery of a Low Exotherm Froth Foam

Permanent change of station orders transferred the patient from San Diego to the U. S. Naval Postgraduate School (NPGS) in Monterey, California. From time to time over several months he reflected on how to better obtain impressions from which to build artificial legs with existing materials. It was felt that if some type of plastic or foam with a low exotherm and the property of expanding on curing could be located, the desired socket (or at least impression) could be achieved. He envisioned the following process:

a. Pull the desired thickness stump sock over the stump.

b. Pull a thin, form-fit release covering (plastic, rubber, etc.) over the stump sock.

c. Insert the covered stump into a pressure-tight container.

d. Pour or force a plastic or foam into the container.

e. Allow the material to expand, pressurize the system (load the stump) and then become firm all in a relatively short period of time.

f. Remove the stump from the container and shape a prosthesis around the socket so formed, providing the material used had physical properties compatible with use as a socket. Otherwise, the impression so made could be used as a form from which to construct a socket.

Obviously the entire concept depended on one primary factor -- locating a low exotherm plastic or foam.

In January 1965 the envisioned process was discussed with a NPGS Department of Aeronautics technician who referred the patient to Aztec Engineering, Seaside, California for information on commercial availability of low exotherm plastics and/or foams. Although personnel at Aztec were unaware of such a material when initially contacted in February, by March 1965 they had discovered a low exotherm, two component, froth foam (polyurethane 202) distributed by Polytron Sales Corporation, Richmond, California.

3.2 Tubular Lucite Impression Cylinder

This "find" shifted efforts to the design of a container into which the stump could be inserted and the foam released. It was felt that the following container criteria would be desireable:

a. Rigid container for repeated use and control of the parameter pressure.

b. Transparent container to observe the action of the foam.

c. Cone shaped or displaceable wall container to facilitate removal of the impression.

d. Materials on hand at NPRL or NPGS.

Based on the above criteria, the first containers were made from six-inch inner diameter, 3/16-inch thick lucite plastic tubing. The wall of these tubes was sawed through on one side so that the tube could be spread apart after foam set-up for easy impression extraction.

A demonstration run was conducted at NPRL during April 1965. The patient's right stump was first covered with a five-ply wool stump sock (the desired sock thickness to be worn with the finished prosthesis) and then a molded polyvinalalcohol (PVA) bag utilized as a release agent. The stump so covered was then inserted in the silicone greased, lucite tube. The tube, with its seam taped shut with masking tape, had a plastic gasket wedged between the patient's thigh and the upper rim of the container. The patient sat in a chair with his stump and the tube held out horizontally while polyurethane 202 foam was dispensed under pressure via nozzle into the open bottom of the container. When the tube was about one half full of foam, the patient stood up in order to close off the tube's open base and to apply some body weight on the foam as it started to harden.

As the foam expanded, it forced its way out of the thigh gasket and the base of the container. Thus, only a portion of the desired pressure was retained. Too, the stump had been poorly centered, so in one region the foam impression was paper thin. A similar procedure was commenced to obtain an impression of the left stump, but during foaming the nozzle became plugged and the run had to be terminated prior to its completion. The entire group then proceeded to the Polytron plant in Richmond to continue the experiment using large cardboard cups merely to further verify the feasibility of the overall idea since it was apparent that the lucite tubes were not going to be satisfactory pressure containers. Granted, significant problems arose during this initial evaluation, but it convinced all observers that the basic method of using the foam and an appropriate container could provide an accurate impression of any portion of the body under various load conditions.

3.3 Aluminum Impression Can (Plexiglass Bottom)

During the fall of 1965 renewed efforts were directed toward the design of a pressure container better adapted to the existing conditions than lucite tubing. Adequate attachments for clamps and hinges were difficult to install. At this point it was felt that sufficient observance of the foam action would be possible merely by using a plexiglass bottom in the pressure container. From the sketch of a split aluminum cylinder with detachable top and bottom, a pressure container similar to the one shown in Fig. 6 was built by the NPGS Machine Facility. The original container had a bottom made of 1/4-inch plexiglass containing a spring-loaded, one-way flapper valve.

In February 1966 the aluminum container with a plexiglass bottom was used at the Polytron plant in Richmond for the second series of tests. The patient's stump was covered with a five-ply wool stump sock and a pre-formed PVA sock as a release surface (Fig. 7). The inner surfaces of the container were coated with silicone, the can's top and bottom attached and the covered stump inserted into the can through the "X" cut in the top's rubber gasket. The "ears" of the "X" were pulled upward then held firmly against the thigh by tightening the web belt shown in Fig. 8. As with the lucite tubes, the container and the stump were held horizontal, foam nozzle inserted in the flapper valve, foam applied around the stump, nozzle removed and patient stood up to apply weight as the foam hardened (Fig. 8).

On the first run insufficient foam was used to build up any significant pressure. On the second try sufficient foam was used; but as pressure built up, the plexiglass bottom fractured allowing foam and pressure to escape. The obvious conclusion was that the pressure container would have to be modified again. Foam characteristics of the polyurethane 502 foam used appeared satisfactory, but this evidence was inconclusive due to the container failure.

3.4 Aluminum Impression Can (Aluminum Bottom)

Since foam action was difficult to observe and seemed to be presenting no problems, an aluminum bottom was built for the can (Fig. 6). The modified container was used on 15 April 1966 at the Polymer plant using procedures similar to those followed in February.

This time pressure was retained and the resulting impressions were very good except for the rough surface caused by the wrinkles in the PVA release bags. Other poor aspects were:

a. The aluminum can's clamps were badly bent from the foam pressure.

b. The container had to be disassembled and reassembled for each impression.

c. The container's inside surfaces had to be greased each time.

d. Control of the pressure was difficult.

e. Foam action could not be observed.

One of the Polytron employees felt that plastic bags were the answer to the pressure container problem.

3.5 Polyethelene Impression Bag

On 10 June 1966 at Fluid Form in San Leandro, California, the patient met with Polymer and Fluid Form personnel to make several impression runs using polyethelene bags for both the inner release surface in contact with the wool stump sock and the outer pressure container. The inner bag made from 1-1/2 mil thick polyethelene was cut and heat-sealed to approximate the dimensions of the stump. The outer pressure bag was made from six-mil thick polyethelene, heat-sealed to form roughly a right circular cylinder with an open top and a small opening in the bottom for insertion of the foam nozzle. A large ring stand with a seven-inch inside diameter, vertically adjustable ring was used to support the outer bag, and to provide a thigh foam seal when the stump was passed down through the ring and the thigh wedged against the inner circumference of the ring.

The unsealed top of the outer impression bag was led up the inside of the ring from the bottom, and then its top edge (about two inches) folded over the outside of the ring. The stump, covered with a five-ply wool stump sock plus the inner polyethelene bag, was inserted firmly down into the ring, and then the upper rim of the inner bag was also folded down over the outside of the ring. The upper rims of both bags so folded were then tightly taped to the outer circumference of the ring forming the foam-tight thigh seal.

Polyurethane 502 foam was admitted into the outer bag by inserting the foam nozzle into the small port left in the bottom of the outer bag. The amount of foam used varied from filling one-third to one-half of the free volume between the inner and outer bags. After admitting the foam, the bottom port was clamped shut to prevent foam and pressure escape.

As the foam rose, air escape vents had to be poked in the top of the impression bag to permit the release of displaced air. These vents, if made by puncturing the outer bag with a knife, resulted in local stress concentrations at the ends of the "slit" which in turn led to bag rupture, pressure loss and a less than optimum impression as depicted in Figs. 9 and 10. This problem was eliminated by making air vents with a circular paper punch only to find that the heat sealed seams of the bag could not sustain the increased desired pressure of two psi over atmospheric pressure. Two psi was chosen as a starting value with the ultimate goal of obtaining impressions at high load conditions (three or four psi) so that all soft tissue would be well compressed.

The same procedures as described above were undertaken again on 12 August 1966 at Fluid Form in San Leandro with extreme care given to heat sealing the outer bags. Once again the outer bags failed along the seams, even when a double seal was used. It was now quite obvious that the foam was not the primary item of concern, for its performance was as had been hoped for, i.e., quite satisfactory impressions were possible. The main concern appeared to be the design of a satisfactory outer pressure container. Polytron personnel stated that a return to a rigid container might be necessary. From the patient's viewpoint this represented returning to a relatively complicated and messy process as compared to the straight-forward plastic bag approach.

3.6 PVC Impression Bag

In an attempt to exploit the advantages of plastic containers, a number of bag, plastics and packaging concerns were contacted. A call to Aztech Industries (formerly Aztec Engineering), Seaside, California revealed the existence of a plastic sealing machine capable of creating a seal as strong as the material itself. Figure 11 shows the drawing from which the first six impression bags were constructed from 15 mil polyvinalchloride (PVC) by Aztech Industries.

Other items of concern were the creation of an air-tight seal between the patient's thigh and the thigh collar of the impression bag (Fig. 11) plus the rough surface of the impressions caused by wrinkles in the non-formfitting inner release bag covering the stump and stump sock. It was decided to use a sphygmomanometer for the thigh collar seal since with it, the amount of pressure holding the collar against the thigh could be easily controlled. To eliminate the rough impression surface, it was decided to use latex balloons nine inches long by inflating them then pushing them (inverting) onto the stump while simultaneously deflating the balloon.

The new materials were tested at Fluid Form in San Leandro on 7 September 1966. A five-ply wool stump sock was pulled snugly onto the stump. A nine inch latex balloon was inflated, pushed onto the sock-covered stump while being deflated, the neck cut off and the balloon rolled the rest of the way over the knee as pictured in Fig. 12. The latex was then well sprayed with silicone to enhance a clean, smooth release between foam and latex. The stump so prepared was thrust into the collar of the impression bag which was pulled far up on the thigh for a very snug fit. The sphygmomanometer was then wrapped firmly around the bag's thigh collar and pumped up to seal off the top of the bag.

Next, the foam nozzle was inserted in the nozzle port and the bag filled with polyurethane 202 foam from one-third to one-half of its free volume. The nozzle was removed, nozzle port clamped shut and the patient stood up (originally seated). As the foam expanded, more pressure was pumped into the sphygmomanometer to insure a foam-tight thigh seal. The Fluid Form employee controlled foam escape and thus internal pressure, by merely pinching the pressure vents with his fingers. As foam set-up commenced, full weight was gradually put on the stump and kept there until the foam became fairly rigid (a period of about five minutes) as depicted in Fig. 13. At the end of the 5 minute period, pressure was bled off the sphygmomanometer, but the stump was left in the foam for an additional ten nimutes to insure a relatively firm impression.

The impression was gently pulled off the stump revealing gratifying results. A precise, wrinkle-free impression of a stump in a loaded condition had been obtained (Figs. 14 and 15) in a fairly simple, transparent container without container failure and with good control of pressure. Four runs (two on each stump) were made that day with the following conclusions:

a. The bag vents should be larger.

b. The overall bag dimensions should be smaller (less volume, less foam, less heat).

c. The overall idea was sound and workable.

3.7 PVC Impression Bag (Revised)

On 8 September 1966, a revised impression bag design was drawn and submitted to Aztech Industries for fabrication of six more bags with reduced dimensions. On 7 October 1966 the revised PVC bags were used at Polymir Industries, Inc. in Hayward, California to verify the overall process -- bag dimensions, type of foam, amount of foam, foam maximum temperature and foam maximum pressure. The same techniques and type of foam used one month earlier in San Leandro were also used for this series of tests. The additional procedures involved the measurement of temperature and pressure.

Temperatures were measured in the warmest region of the bag, near the distal end of the stump close to the center of the impression, by piercing the outer bag after the foam had started to set and there inserting a thermometer into the foam. Pressures were measured by inserting into the impression bag a sphygmomanometer modified by reducing the size of the air bladder appreciably, then resealing the cut edges. This unit was placed inside the upper portion of the impression bag with the pressure tubes running out one of the pressure vents. Just enough air was pumped into the modified sphygmomanometer to record a change of pressure in that air sample as the foam expanded and pressurized the system.

Temperatures vaired from 163^{o}F to 181^{o}F maximum and reached this value about 10 minutes after the foam began to harden. Pressure changes ranged from 1.57 psi to 2.09 psi. The conclusions reached from this series of tests were:

a. The polyurethane 502 foam was the better of the two foams used up to this time, but quite likely there is still a better foam available.

b. The greater the pressure obtained in making an impression, the better the comfort both during foaming and when standing in the impression many days after foaming.

c. The reduced bag dimensions were satisfactory, but could be made still smaller.

3.8 <u>Tapered PVC Impression Bag</u>

Due to Aztech Industries going out of business, the drawing for tapered PVC pressure bags (Fig. 16) was submitted to the Jobst Institute, Inc., Toledo, Ohio for the fabrication of six reduced volume impression bags made from twelve mil thick PVC. These bags were used at the Polymir plant in Hayward on 26, 30 and 31 May 1967 to evaluate both the impression bag design and a new higher density foam mix. The steps followed were the same as those described in Section 3.6 and used at Fluid Form in San Leandro on 7 September 1966.

The performance of the tapered bags was excellent. Good control of pressure was possible due to the adequate strength of all seams. Satisfactory distribution of foam was possible with one of the pressure vents closed throughout the process. This will simplify bag fabrication by eliminating one pressure vent. General bag dimensions for the stumps involved were quite satisfactory.

The same degree of success was not shared by the foam used. Due to a poor mix ratio of catalyst to resin, the foam was too flexible (even tacky in places) and full of voids. This produced impressions significantly inferior to previous ones using PVC impression bags.

Conclusions reached as a result of these runs were:

a. The higher density foam is desirable, but it must incorporate optimum component ratio and mixing.

b. The tapered PVC impression bags are completely satisfactory. For even better foam distribution, the base dimension of eight inches shown in Fig. 16 should be reduced to seven inches and the upper twelve inch figure increased to thirteen inches. To achieve even higher pressures, the bags could be made from thicker PVC.

c. The metal-catch type sphygmomanometer with an extension link added to the regular catch provided a completely satisfactory thigh seal.

d. The nine-inch latex balloons provided an excellent form-fit surface covering for the stump and stump sock, but they were difficult to roll over the knee and to keep high up on the thigh (especially on the longer stump). A tapered latex sock would be easier to work with.

Since the foam impression phase of research had produced a number of satisfactory impressions, consideration could then be given to the evaluation of sockets made from this process.

SECTION 4

EVALUATION OF PROSTHESIS SOCKET MADE FROM FOAM IMPRESSION

4.1 Positive Cast

The desired goal of making a precision, weight bearing impression from a foam suitable for use as the prosthesis socket has not been achieved at this writing. Therefore, the conventional positive casts (plaster reproductions of the stumps) shown in Fig. 17 were made from the foam impressions of Fig. 15. These particular impressions represented the best test results from the standpoint of high pressure retention and a smooth surface of all the impressions discussed in Section 3. The positive casts were made in order to build check sockets initially, and ultimately to build finished sockets for experimental prostheses.

4.2 Check Socket

From the positive casts mentioned in Section 4.1, the check sockets shown in Fig. 18 were built. These were hard plastic sockets made to verify intimacy of fit and degree of comfort. The patient stood in these check sockets for a period of about 20 minutes and experienced moderate discomfort only on the distal end of each stump. That does not mean that no other portion of either stump was sustaining an uncomfortable load; but that if such were the case, it was being overridden by the stronger impulses from the distal end. The patient's discomfort while standing in a hard plastic check socket, which represented an accurate imprint of the stump area under loading conditions, may be partially attributed to the lack of resiliency of the surface. This viewpoint is born out by comments made in Section 3.7 where the foam imprint, even after curing, provided a comfortable fit. To insure that areas of the stump other than the distal end were not uncomfortably loaded, relief of distal end loads was necessary.

The remaining procedures discussed in this Section have not been completed at this writing, but they will be conducted and reported on by NPRL.

4.3 Relief for Stump's Distal End

One common way of providing for load relief on the distal end of the stump is to add a significant amount of plaster (1/4 inch or more) to that portion of the positive cast which in effect lengthens the socket. This is considered undesirable since the basic idea of the foam impression method is to form a usable socket directly or at least minimize the number and magnitude of the modifications the prosthetist must make.

It is believed that a better approach to the relief problem would be to place the relief material (leather, Kemblo rubber, etc.) right on the critical area of the stump, underneath the wool stump sock and latex release sock. The foam impression would then be taken in the manner described in Sections 3.6 and 3.8, and would yield an impression with built-in relief. From this impression a check socket incorporating only distal end relief could be built.

4.4 Relieved Check Socket

With satisfactory foam, the impression obtained in Section 4.3 would constitute the relieved check socket. Otherwise, it would provide the mold for a positive cast from which to build the check socket. It is felt that the patient's response and stump tissue coloring after standing for some time in this socket would be most meaningful.

Significant discomfort in any one area on the stump would likely indicate the need for relief in that area. A bright pink coloring of the stump would indicate an area of significant load bearing. It might be desirable to distribute this load concentration over a larger area simply to reduce the magnitude of peak pressures. Care should be taken to avoid choking or wedging the stump in the socket. Even if no discomfort were noted, blood supply would be restricted and capillaries crushed. The final result would be a poorly nourished stump, but it might take weeks or even months to detect the problem.

Assuming that no discomfort was encountered by the patient, a prosthesis incorporating the check socket could be made for evaluating. If wedging, choking or sinking to the bottom of the socket were encountered while the patient stood in the check socket, increased load bearing in the patella, popliteal and medial and lateral condyle areas likely would correct the situation. Some prosthetists feel that such modifications plus that for the stump's distal end represent the absolute minimum required for satisfacotry BK prosthesis construction.

4.5 Patella, Popliteal, Condyle Modifications

Increasing the socket pressure exerted on the stump in the patella, popliteal, and condyle regions requires a procedure just the opposite of that used for relieving as discussed in Section 4.3. Increasing the load requires a socket modification which reshapes and decreases the inside measurements of the socket. Such modifications, like the reliefs, could be accomplished in essentially one of two ways.

Using the positive cast approach, plaster must be judiciously carved away from the areas where an increase in load is desired. Heretofore, this has usually amounted to removing a moderate amount of plaster from a small area across the patellar tendon to create the patellar shelf in the finished socket and an amount, dependent upon initial stump size, of plaster from a larger area of the popliteal region to create the popliteal bulge.

If the finished socket is derived directly from the foam impression; and increased loads are required in given areas, then the impression itself would have to be built up with additional foam in the areas requiring additional loading. This procedure would amount to just the reverse of that described in the preceding paragraph, and the socket so modified could then be used as a check socket.

4.6 Modified Check Socket

The modified check socket would be constructed from the modified positive cast or the modified foam impression (both described in Section 4.5). It would be used in the same manner as discussed in Section 4.4 to determine the feasibility of using such a modified socket in an evaluation prosthesis. Such a prosthesis could be anything from the temporary pylon type to a conventional BK prosthesis.

4.7 Evaluation Prosthesis

It should be kept in mind that the foam impression process is designed to eliminate as many intermediate BK prosthesis production steps as possible. For this reason, an evaluation prosthesis should be built as early in the process described in this Section as appears prudent.

In the interest of economy and since the foam process is still in the research and development stage, it would seem reasonable to use a pylon type of construction for the evaluation prosthesis. Such a prosthesis would consist of the check socket connected to a foot by means of an adjustable aluminum pipe.

The wearing of the evaluation prosthesis during various patient activities should be carefully and continually monitored by a research prosthetist to completely and accurately determine advantages and disadvantages of the foam impression technique. It is felt that miniature force transducers placed between the socket and the patient's stump at various locations would greatly facilitate the prosthetist's evaluation.

SECTION 5

MINIATURE TRANSDUCER FOR MEASURING LOCALIZED PRESSURE BETWEEN STUMP AND SOCKET

5.1 Preliminary Considerations

During September 1966, the patient also directed his interests toward the design of an inexpensive transducer to measure selected localized pressures between an amputation stump and the prosthesis socket. It was felt that such an instrument would reveal the magnitude of the load actually being carried at a given location on the stump, the load that could be carried there (insert shims between the stump and stump sock) and the optimum distribution of the total load.

The single most important requirement was that the device fit between the stump and the socket wall without significantly increasing the existing stump tissue loading in the measurement region and thus provide meaningless results. For this reason, it was planned to make the transducer as thin as possible with a maximum thickness of 0.025 inch. Additional requirements were repeatable readings, readings available over the entire patient activity range (lying down to running and jumping) plus freedom and ease of placement of the device at any location in the socket.

Thought was given to the use of optical, mechanical and electrical means of measuring the subject forces. Optics were ruled out due to line-of-sight inaccessibility of the region in question. Mechanics were rejected due to probable size of the required device. By elimination, an electrical transducer appeared quite logical as a reasonable means for obtaining the desired data. It was felt that either a change in resistance or capacitance could be utilized in designing a suitable transducer.

A search of library information and available technical publications yielded ample general information on electrical measurements, capacitors, etc., but nothing specific on the design of the type of transducer required.

5.2 Capacitance Transducer

The idea of building a very small transducer operating on a change in capacitance, created by a force reducing a solid dielectric thickness between two parallel conducting plates, was considered. The feasibility of building such a transducer was briefly discussed with faculty in the Aeronautics, Electronics, and Chemistry Departments of NPGS. A variety of opinions was expressed; but all felt the basic idea was sound, so the selection of suitable, available materials was commenced. According to Bloomquist[11], C = KA/d.

Where: C = capacitance (μf)

K = dielectric constant (μf/m)

A = conducting plate effective area (m^2)

d = dielectric thickness (m)

Relatively high values of capacitance were desired in order to realize more significant changes in C. To achieve this, it was desirable to use a dielectric with a high K value, as large a conductor surface area as the problem would permit and as thin a dielectric as applied voltage and ultimate dielectric strength allowed.

Brotherton[12] states that conducting plate losses could be reduced by using metals of low resistivity and increasing the plate thickness. The obove conditions were strived for commensurate with the materials on hand at NPGS. Brass shim stock (0.003 inch thick, resistivity = $6 - 8 \times 10^{-8}$ ohm meters) and aluminum foil (0.005 inch thick, resistivity =

2.73×10^{-8} ohm meters) were used for conducting plates. Teflon (0.004 inch thick, K = 2.1 @ $22^{o}C$) and mylar (0.008 inch thick, K = 2.48) were used as dielectric materials.

Sandwich construction incorporating alternating layers of conducting material (wafers) and dielectric material was used for transducer fabrication. On the transducers with multiple conducting wafers, the exposed ends of alternating wafers were electrically welded to each other and then to a 28-gauge, insulated wire lead. The completed unit was then enclosed in mylar tape.

Conductor/dielectric combinations included brass/mylar, brass/teflon and aluminum/teflon with the number of conducting plates ranging from two to nine (Table I and Fig. 19). Overlapping wafer area was 1/4 square inch on all models except Model F where the area was 1/8 square inch. Capacitance change on that transducer was so much below its 1/4-inch counterparts, that Model F was not included in evaluations other than the comparative data listed in Table I.

Each transducer was then loaded and unloaded with varying loads to check its repeatability which appeared to be quite satisfactory on most of the units. Next, each model was loaded with the same load and its change in capacitance recorded. These results are listed in Table I and clearly show that Model D (brass/mylar, nine wafers) gave the greatest change. Table I also shows that on a two wafer comparison basis, the brass/mylar combination gave the best results. On the basis of these tests, Model D was selected to be calibrated and tested in the socket.

To calibrate the transducer, consideration was given to both displacement and force. First, Model D was compressed and relaxed repeatedly between the faces of a micrometer. Capacitance readings for a given displacement were taken and recorded in Table II. These values were then plotted in Fig. 20 as displacement (δ) vs. C. Second, capacitance readings were recorded in Table III as known weights were applied to a known surface area of Transducer D to provide loading information in pounds per square inch. These data are plotted in Fig. 20 as load intensity in psi (P) vs. C.

Finally, the same transducer was inserted in the middle of the patellar shelf of the left prosthesis and capacitance readings from a Heathkit Capacitor Checker, Model C-3 were taken at certain phases of standing and walking and while sitting. These results are listed in Table III. Corresponding load conditions for each leg position were then readily obtained from the P vs. C curve of Fig. 20 and recorded in the "Load" column of Table III.

The results were most encouraging since they agreed quantitatively very well with data collected by the University of California (Berkeley) Biomechanics Laboratory and with the nervous sensations experienced by the patient. As seen in Table III, socket loads on the Patellar Tendon ranges from 0.65 psi while sitting to over 32 psi while walking with full weight on the ball of the left foot. This preliminary research indicated that the use of capacitance transducers might be feasible and that further investigation was warranted. It appeared that the use of more desirable materials, i.e., copper with a resistivity of 1.71×10^{-8} ohm meters and clear ruby muscovite mica with a K of 7.0 @ 25^{o}C, might produce even better results.

5.3 Resistance Transducer

A perusal of sales catalogues from companies producing various electronic measuring devices prompted correspondence with Clark Electronic Laboratories (CELAB), Palm Springs, California who advertised a versatile pressure sensitive paint for transducer construction. A CELAB engineer recommended using their Micro-Ducer Pressure Sensitive Paint, Type 3-A, for the miniature transducers required.

CELAB instructions[13] for the use of pressure sensitive paint were followed closely in the construction of the resistance transducers. A piece of brass shim stock .003-inch thick was lightly sanded and cleaned well on both sides with acetone. Wafers of brass 1/4-inch in diameter were cut from the cleaned shim stock with a standard three-hole paper punch. These wafers were then flattened by firmly rolling a small, solid aluminum cylinder over them several times. Next, the flattened, insulation-stripped end of a 28-gauge, insulated lead wire was electrically welded to each of the wafers.

The pressure sensitive paint was stirred well, then one small drop of it placed in the center of a wafer using a .063 inch diameter pointed, metal applicator. The spot of paint so deposited was approximately 1/8-inch in diameter which left a 1/16-inch bare brass rim on the wafer. After the pressure sensitive paint dried, GE RTV-102 white silicone adhesive was applied to the bare brass rim and a second "unpainted" wafer glued to the first. The completed transducer was then enclosed in mylar tape after the adhesive had dried.

The response of the transducers was observed from the loading procedure described in Section 5.2 and was immediately seen to be unrepeatable and unreliable. It was felt that the poor results were due to using partially dried out paint thinned with a thinner other than that recommended by CELAB.

In October 1966, a new one ounce bottle of type 3-A paint was purchased from CELAB and more transducers were built per the procedures in Section 5.3. This time, however, wafers were made from .0020, .0045 and .010-inch thick brass shim stock. Three transducers of each of the three brass thicknesses were built. Known weights were placed on a pan suspended on a rod and knife edge bracket, which in turn were supported by a 1/4-inch cylindrical brass button resting on the transducer. As loads were applied to the transducers, measurements of resistance (R) were obtained from a Simpson Vacuum Tube Voltmeter, Model 312.

The very poor response and/or repeatability of all nine transducers is recorded in Table IV.

In a final attempt to exploit the properties of the pressure sensitive paint, wafers of .010-inch thick cleaned brass were punched in diameters of .1562, .1250 and .1093 inch with a leather punch then rolled flat. A flattened 28-gauge wire lead was electrically welded to one side of each wafer and the other side completely covered with a spot of the CELAB paint. These smaller diameter wafers were then placed on top of .010-inch thick, .250 inch diameter, "unpainted" wafers and held in place solely with mylar tape applied externally around both wafers. These revised transducers were loaded as described above and the results listed in Table V.

The data collected showed an overall improvement in response as evidenced by the shift to the R x 100 scale on the Simpson Voltmeter for the two smaller diameter units. However, repeatability and drift (resistance change with no load change) were as poor as previously encountered, so no further investigation of the CELAB Pressure Sensitive Paint seemed prudent. Samples of the transducers designed are shown in Fig. 19.

SECTION 6

CONCLUSIONS AND RECOMMENDATIONS

The UCB PTB Air Cushion Socket prostheses now being worn by the patient seem markedly superior to any of his previous artificial limbs. They provide greater comfort for longer wearing time periods. It is concluded that the resilient interface they provide between approximately the distal two-thirds to three-quarters of the stump and the socket is a desirable BK prosthesis design parameter. The slight reduction in proximal loading and corresponding relatively uniform increase in distal loading appears to be another desirable feature of these sockets.

At this writing the material used for making the foam impression is physically not satisfacoty for use as the finished prosthetic socket. It is felt, however, that this problem will be overcome in the near future simply through the rapidly advancing state of the art in the field of plastics and foams. The existing foam does suffice quite nicely for obtaining the desired precision impression of a loaded stump. The use of two-component froth foam in conjunction with the tapered PVC impression bags permits excellent detailed impressions to be achieved.

The observation made during foam impression casting, viz. that greater standing comfort existed at the higher foaming pressures, indicates that higher-magnitude forces normal to the surface of the stump, with their correspondingly higher magnitude vertical components to react the body's weight, tend to reduce sinking (bottoming out) in the impression, compressing foam distally and increasing stump distal end loads. Thus, an initial experimental check socket should be made from a "high pressure" foam impression (three psi or greater).

From the one check socket made utilizing the foam impression technique it was apparent that the amount of modifying required by the prosthetist was reduced significantly. This means a corresponding reduction in manufacture time and expense. Another item of importance to a limb shop or a hospital is the fact that the foam process represents a much cleaner method of casting than that of using plaster.

With regard to the miniature load-sensing transducers, it was concluded that the capacitance-type tranducer was worthy of additional research and evaluation. More desirable materials should be considered for fabrication to reduce the overall transducer thickness. The best capacitance transducer, Model D, was 0.038-inch thick, whereas maximum desired thickness was only 0.025-inch. Resistance transducers made with the CELAB pressure sensitive paint could not be made to function satisfactorily.

It is recommended that the experimental steps discussed in Section 4 be followed in order to fully evaluate the merits of the foam impression method of building prostheses, since initial investigations indicate the process has considerable potential. A variety of stump types (boney, fleshy, scarred, etc.) should be utilized in this evaluation in order to verify the validity of the foam technique for all stump types.

A froth foam with physical, chemical, and biological properties commensurate with its use as a prosthesis socket should be developed if the research on the foam impression method indicates such action is warranted.

It is further recommended that the relationship between the relatively high degree of comfort provided by both the air cushion socket and the foam impression be investigated in greater detail to determine similarities. In particular, resiliency and load distribution on the stump should be considered.

TABLE I

CAPACITANCE TRANSDUCER MATERIAL COMPARISON

Model Code	Transducer Thickness (in.)	Wafer Material	Number of Wafers	Dielectric Material	Capacitance ($C, \mu f$)		
					Unloaded	Loaded	$\Delta C \times 10^6$
A	.012	Brass	2	Mylar	.000026	.000050	24
B	.031	↓	5	↓	.000075	.000130	55
C	.041	↓	7	↓	.000150	.000200	50*
D	.038	↓	9	↓	.000150	.000300	150
E	.016	↓	3	Teflon	.000025	.000030	5
F	.047	↓	2	↓	.000020	.000021	1
G	.015	Aluminum	2	↓	.000009	.000011	2

* Non-uniform Construction on This Transducer.

TABLE II

CAPACITANCE TRANSDUCER "D"

DISPLACEMENT VS. CAPACITANCE

Micrometer Reading (in.)		Displacement (δ, in.)	Capacitance ($C, \mu f$)
.037	Fully Compressed	.014	.000235
.039		.012	.000217
.041		.010	.000178
.043		.008	.000161
.045		.006	.000150
.047		.004	.000143
.049		.002	.000136
.051	Relaxed	.000	.000123
.049		.002	.000132
.047		.004	.000137
.045		.006	.000144
.043		.008	.000160
.041		.010	.000183
.039		.012	.000217
.037	Fully Compressed	.014	.000236
.039		.012	.000214
.041		.010	.000181
.043		.008	.000160
.045		.006	.000146
.047		.004	.000134
.049		.002	.000130
.051	Relaxed	.000	.000123

TABLE III

CAPACITANCE TRANSDUCER "D"

LOAD VS. CAPACITANCE

Weight (lb)	Load (P, psi)	Capacitance (C, μf)		
		Run 1	Run 2	Run 3
.000	.000	.000123	.000130	.000123*
.058	.928	.000153	.000162	.000170
.158	2.527	.000197	.000202	
.258	4.130	.000213	.000216	
.358	5.725	.000217	.000223	
.458	7.325	.000221	.000227	
.558	8.940	.000221	.000221	.000231
1.058	16.920	.000237	.000234	
1.558	24,920	.000237	.000238	
2.058	32.920	.000238	.000239	.000233
4.058	64.900	.000232	.000242	
5.058	80.800	.000241		
6.058	96.950	.000233	.000242	
8.058	128.900	.000237		
10.058	160.900	.000244		
12.058	192.800			
14.058	224.800			
16.058	256.800			
18.058	288.800			
20.058	320.700			
Sitting	.65	.000155	.000152	
Standing, 2 Legs	6.80	.000224	.000220	
Standing, 1 Leg	16.80	.000235	.000233	
Walking, Heel Contact	4.53	.000216		
Heel Loaded	8.90	.000227		
Foot Flat	5.70	.000220		
Ball Loaded	32.00	.000242		
Toe Off	6.80	.000223		

* Ten minutes after unloading.

TABLE IV

RESISTANCE TRANSDUCERS

BRASS/PRESSURE SENSITIVE PAINT

Model Code	Wafer Thickness (in.)	Overall Thickness (in.)	Resistance (R x 1000 ohms)					
			Unloaded		5.35 psi		15.55 psi	
			Run 1	Run 2	Run 1	Run 2	Run 1	Run 2
a	.0100	.037	12.5	14.6	6.6	5.1	2.6	4.3
b		.033	21.2	50.0	30.0	11.7	6.0	5.2
c		.037	300.0	800.0	14.0	4.2	9.5	2.4
d	.0045	.023	∞	∞	100	700	50	28
e		.022	74	60	32	32	31	26
f		.022	∞	∞	∞	∞	500	400
g	.0020	.018	∞	∞	∞	∞	∞	∞
h		.020	∞	∞	∞	∞	∞	∞
i		.017	∞	900	19.0	6.7	8.5	5.8

Area $= \pi d^2/4 = 3.14(.25)^2/4 = .0491$ in^2

Weight: cylinder = .0029 lb
pan/rod = .0595 lb
weights = .1000 lb

Load: unloaded = weight/area = 0/.0491 = 0 psi
cylinder/pan/rod/2 weights = .2624/.0491 = 5.35 psi
cylinder/pan/rod/7 weights = .7624/.0491 = 15.55 psi

TABLE V

RESISTANCE TRANSDUCERS (MODIFIED)

BRASS/PRESSURE SENSITIVE PAINT

Model Code	Painted Wafer Diameter (in.)	Resistance (R ohms)						
		Unloaded		.2426 lb		.7426 lb		
		Run 1	Run 2	Run 1	Run 2	Run 1	Run 2	
j	.1562	∞	∞	35	60	17	150	R x 1000
k	↓	∞	∞	350	210	110	350	R x 1000
l	.1250	45	76	23	8.8	10.5	19.7	R x 100
m	↓	41	86	34	52	29	47	R x 100
n	.1093	1000+	∞−	1000	68	250	73	R x 100
o	↓	450	1000+	400	680	85	150	R x 100

Diameter of all unpainted wafers = .250 in.

Thickness of all wafers = .010 in.

Significant drift on all readings.

1 patella

2 patellar tendon

3 condyle

4 tibia

5 fibula

6 distal end

Fig. 1 Patient's Amputation Stumps

Fig. 2 Marked Cast Sock

Fig. 3 Conventional Wrap Cast

Fig. 4 PTB Wrap Cast

Fig. 5 Air Cushion Socket Prostheses

Fig. 6 Aluminum Impression Can

Fig. 7 PVA and Wool Covered Stump

Fig. 8 Foamed Stump in Aluminum Can

Fig. 9 Polyethelene Bag Air Vent Rupture

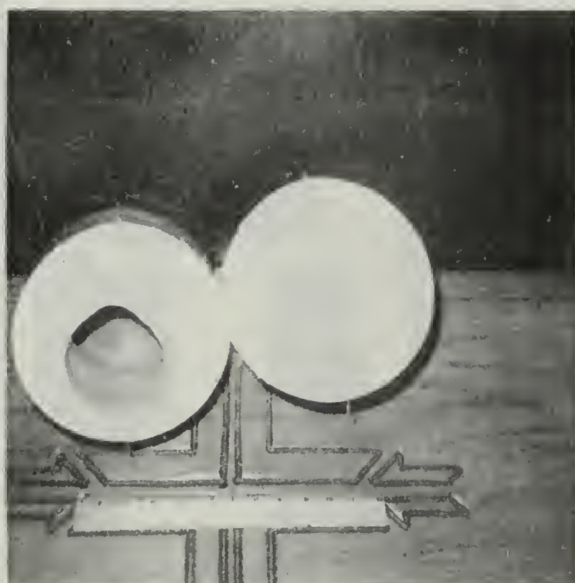
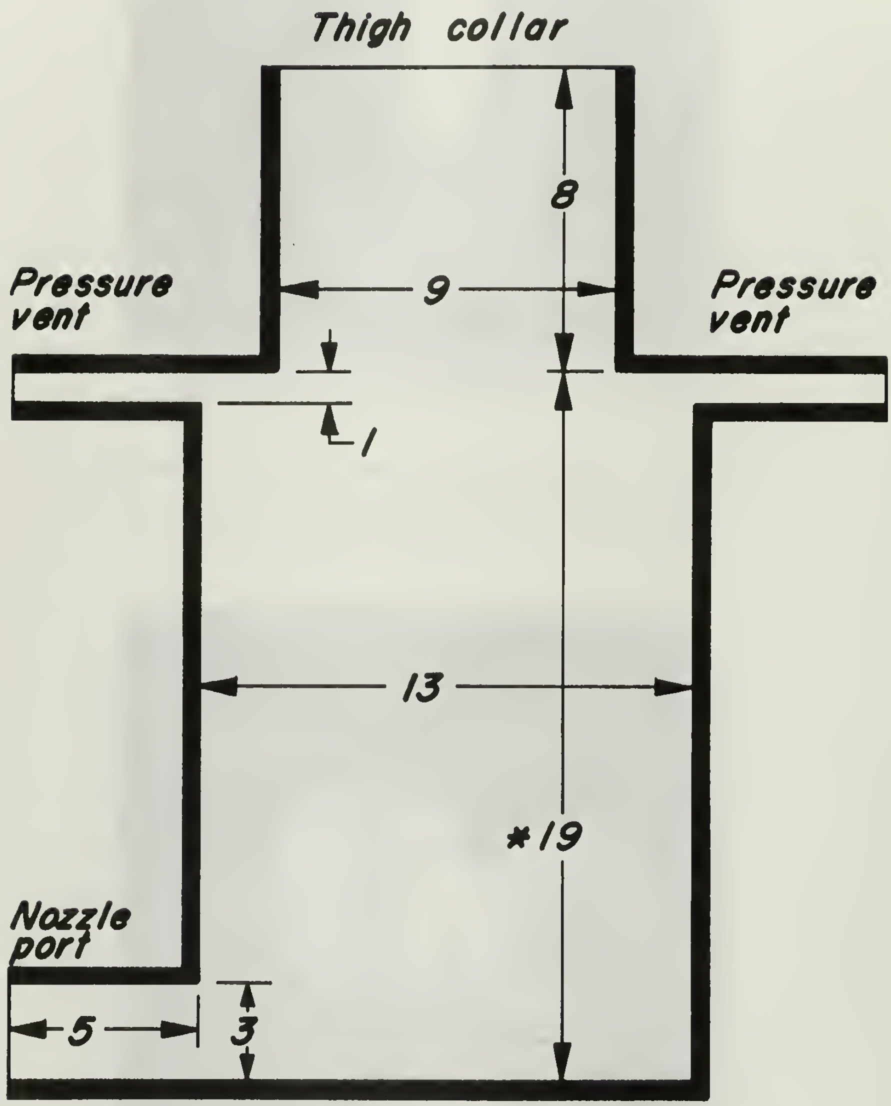


Fig. 10 Polyethelene Bag Impression Cross-section

FIGURE 11
PVC IMPRESSION BAG



* For small bag use 15 inches.

▬ Seam line.

Dimensions are for material lying flat on work table.

Fig. 12 Latex and Wool Covered Stump

Fig. 13 Foamed Stump in PVC Bag

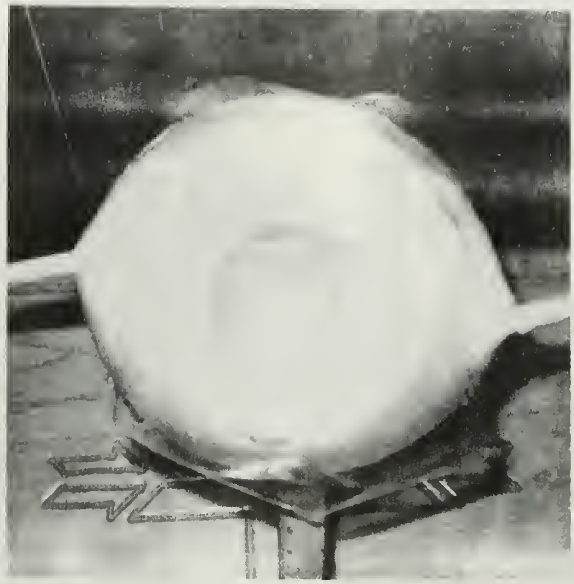


Fig. 14 Stump Impression in PVC Bag

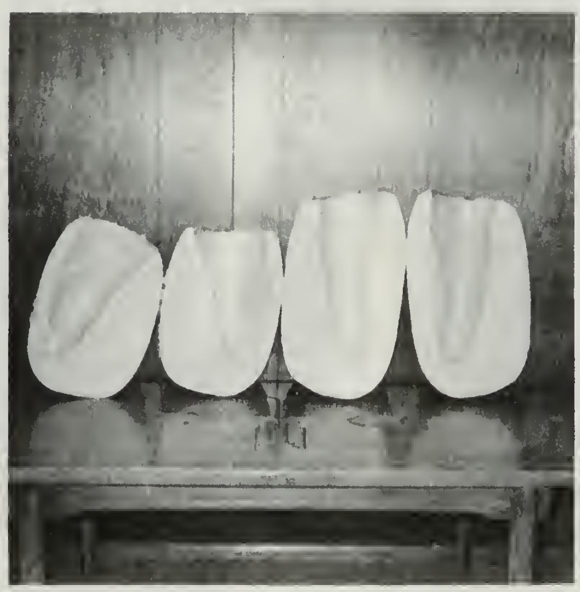
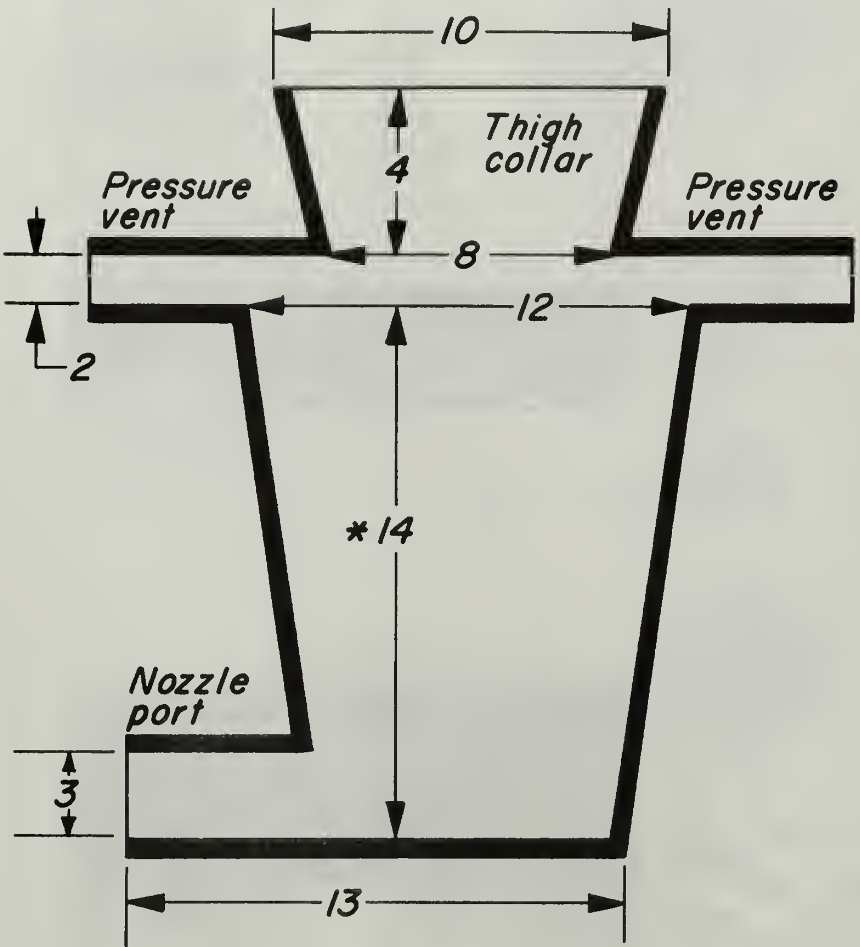


Fig. 15 Impression Cross-sections in PVC Bags

FIGURE 16
TAPERED PVC IMPRESSION BAG



*For large bag use 17 inches.

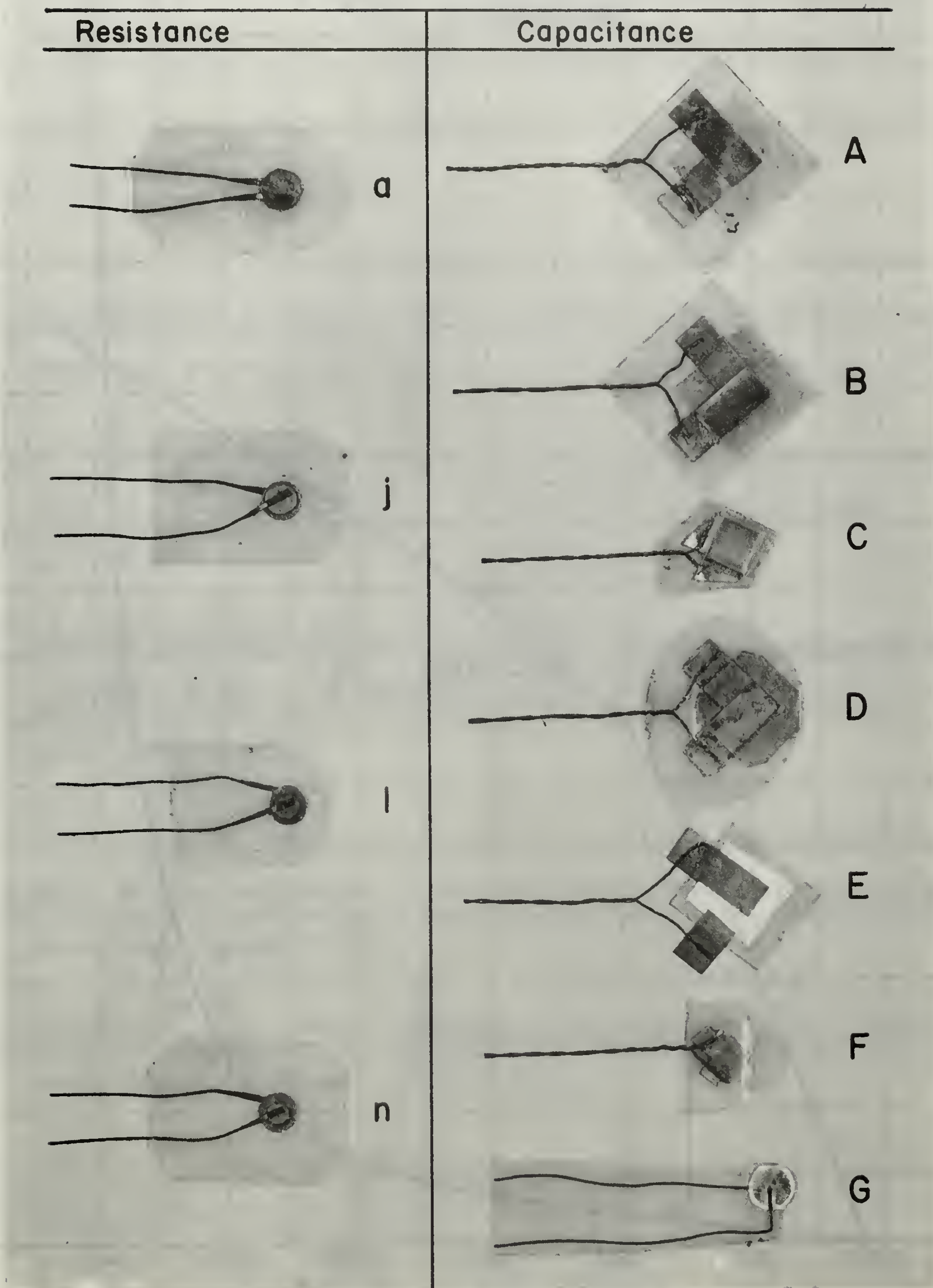
Seam line. (desire 5 psi capability)

Dimensions are for material lying flat on work table.

Fig. 17 Positive Casts

Fig. 18 Check Sockets

FIG. 19 TRANSDUCER MODELS



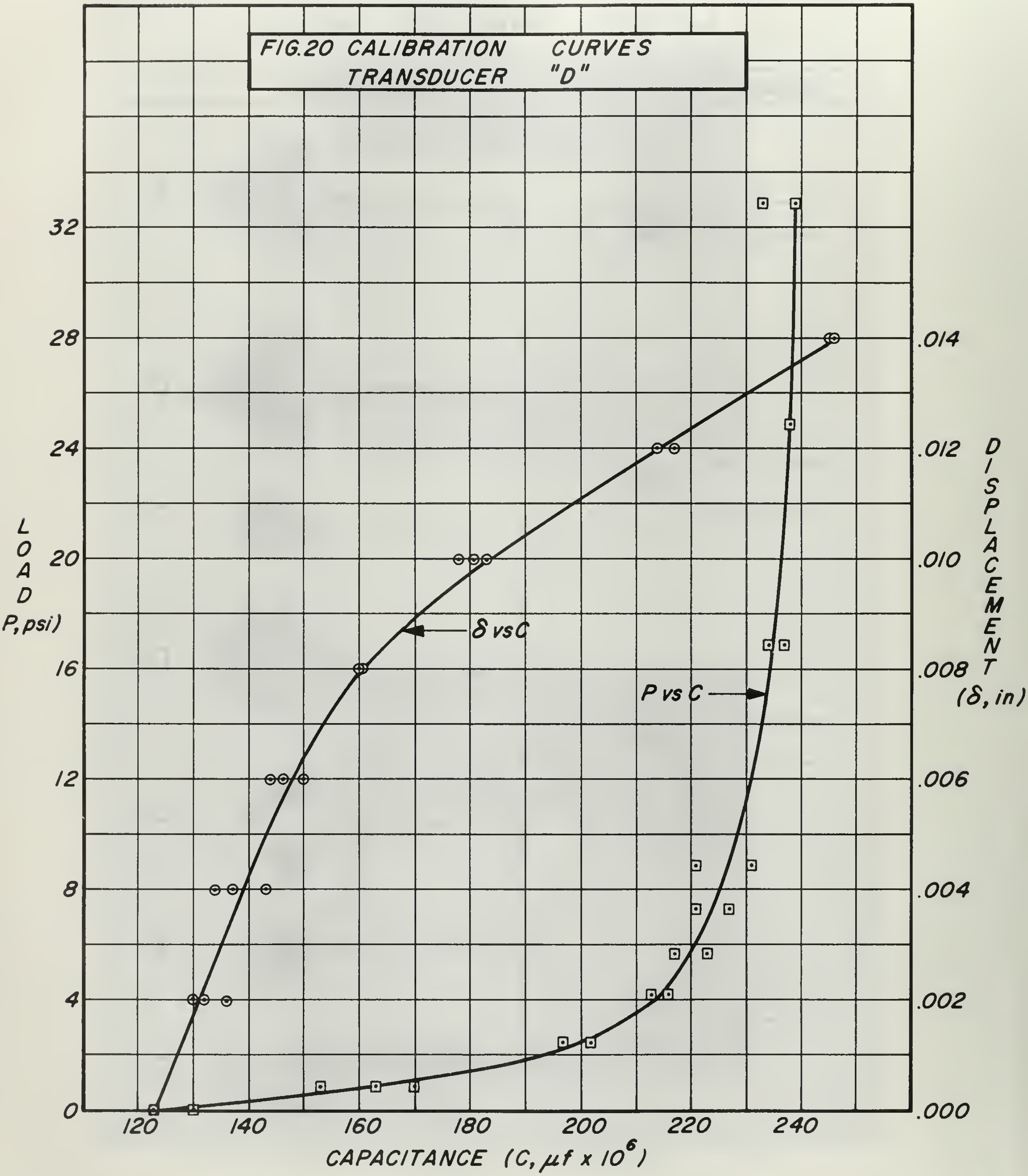


FIG.20 CALIBRATION CURVES
TRANSDUCER "D"
LOAD (P, psi)
0
4
8
12
16
20
24
28
32
DISPLACEMENT (δ, in)
.000
.002
.004
.006
.008
.010
.012
.014
120
140
160
180
200
220
240
CAPACITANCE (C, μf x 10^6)
δ vs C
P vs C

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13. ABSTRACT

A brief summary of the historical development of artificial limbs is followed by a detailed history of the below-knee prostheses worn by the author. Next, the development of a method of obtaining a precision, weight bearing impression of an amputation stump using a low exotherm, two-component froth foam, with a method of evaluating a prosthesis socket made from said impression, is given. Finally, some experimental research into the design of an inexpensive, miniature transducer for measuring localized pressure between the amputation stump and the prosthesis socket is discussed.

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below-knee						
impression						
foam						

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